

106TH CONGRESS  
2D SESSION

# H. R. 5235

To ensure the timely availability of generic drugs through enhancement of drug approval and antitrust laws enforced by the Food and Drug Administration and the Federal Trade Commission regarding brand name drugs and generic drugs.

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## IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 20, 2000

Mr. WAXMAN (for himself, Mr. STARK, Mr. BROWN of Ohio, Mr. BERRY, Mr. COBURN, and Mr. DEUTSCH) introduced the following bill; which was referred to the Committee on Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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## A BILL

To ensure the timely availability of generic drugs through enhancement of drug approval and antitrust laws enforced by the Food and Drug Administration and the Federal Trade Commission regarding brand name drugs and generic drugs.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

3       **SECTION 1. SHORT TITLE.**

4       This Act may be cited as the “Prescription Drug  
5       Competition Act of 2000”.

1 **SEC. 2. FINDINGS.**

2 Congress finds that—

3 (1) prescription drug costs are increasing at an  
4 alarming rate and are a major concern of senior citi-  
5 zens and American families;

6 (2) there is a potential for drug companies own-  
7 ing patents on brand-name drugs to enter to private  
8 financial deals with generic drug companies in a  
9 manner that could tend to restrain trade and greatly  
10 reduce competition and increase prescription drug  
11 costs for American citizens; and

12 (3) enhancing competition between generic drug  
13 manufacturers and brand name manufacturers can  
14 significantly reduce prescription drug costs to Amer-  
15 ican families.

16 **SEC. 3. PURPOSE.**

17 The purposes of this Act are—

18 (1) to provide timely notice to the Food and  
19 Drug Administration and the Federal Trade Com-  
20 mission regarding agreements between companies  
21 owning patents on branded drugs and companies  
22 who could manufacture generic or bioequivalent  
23 versions of such branded drugs; and

24 (2) by providing timely notice, to—

25 (A) ensure the prompt availability of safe  
26 and effective generic drugs;

1 (B) enhance the effectiveness and effi-  
2 ciency of the enforcement of the antitrust laws  
3 of the United States; and

4 (C) deter pharmaceutical companies from  
5 engaging in anticompetitive actions or actions  
6 that tend to unfairly restrain trade.

7 **SEC. 4. DEFINITIONS.**

8 In this Act:

9 (1) AGREEMENT.—The term “agreement”  
10 means an agreement under section 1 of the Sherman  
11 Act (15 U.S.C. 1) or section 5 of the Federal Trade  
12 Commission Act (15 U.S.C. 45).

13 (2) ANTITRUST LAWS.—The term “antitrust  
14 laws” has the same meaning as in section 1 of the  
15 Clayton Act (15 U.S.C. 12), except that such term  
16 includes section 5 of the Federal Trade Commission  
17 Act (15 U.S.C. 45) to the extent that such section  
18 applies to unfair methods of competition.

19 (3) ANDA.—The term “ANDA” means an Ab-  
20 breviated New Drug Application, as defined under  
21 section 505(j) of the Federal Food, Drug and Cos-  
22 metic Act.

23 (4) BRAND NAME DRUG COMPANY.—The term  
24 “brand name drug company” means a person en-  
25 gaged in the manufacture or marketing of a drug

1 approved under section 505(b) of the Federal Food,  
2 Drug and Cosmetic Act.

3 (5) COMMISSION.—The term “Commission”  
4 means the Federal Trade Commission.

5 (6) FDA.—The term “FDA” means the United  
6 States Food and Drug Administration.

7 (7) GENERIC DRUG.—The term “generic drug”  
8 means a product that is the subject of an ANDA.

9 (8) GENERIC DRUG APPLICANT.—The term  
10 “generic drug applicant” means a person who has  
11 filed or received approval for an ANDA under sec-  
12 tion 505(j) of the Federal Food, Drug and Cosmetic  
13 Act.

14 (9) SECRETARY.—The term “Secretary” means  
15 the Secretary of Health and Human Services.

16 **SEC. 5. NOTIFICATION OF AGREEMENTS AFFECTING THE**  
17 **SALE OR MARKETING OF GENERIC DRUGS.**

18 A brand name drug company and a generic drug ap-  
19 plicant that enter into an agreement regarding the sale  
20 or manufacture of a generic drug that the Secretary has  
21 determined is the therapeutic equivalent of a brand name  
22 drug that is manufactured or marketed by that brand  
23 name drug company, or for which the generic drug appli-  
24 cant seeks such a determination of therapeutic equiva-  
25 lence, and which agreement could have the effect of lim-

1 iting the research, development, manufacture, marketing,  
2 or selling of a generic drug that has been or could be ap-  
3 proved for sale by the FDA pursuant to an ANDA, shall  
4 file with the Commission and the Secretary the text of  
5 the agreement, an explanation of the purpose and scope  
6 of the agreement, and an explanation of whether the  
7 agreement could delay, restrain, limit, or in any way inter-  
8 fere with the production, manufacture, or sale of the ge-  
9 neric version of the drug in question.

10 **SEC. 6. FILING DEADLINES.**

11 Any notice, agreement, or other material required to  
12 be filed under section 5 shall be filed with the Commission  
13 and the Secretary not later than 10 business days after  
14 the date the agreement is executed.

15 **SEC. 7. ENFORCEMENT.**

16 (a) CIVIL FINE.—Any person, or any officer, direc-  
17 tor, or partner thereof, who fails to comply with any provi-  
18 sion of this Act shall be liable for a civil penalty of not  
19 more than \$20,000 for each day during which such person  
20 is in violation of this Act. Such penalty may be recovered  
21 in a civil action brought by the United States, or brought  
22 by the Commission in accordance with the procedures es-  
23 tablished in section 16(a)(1) of the Federal Trade Com-  
24 mission Act (15 U.S.C. 56(a)).

1 (b) COMPLIANCE AND EQUITABLE RELIEF.—If any  
2 person, or any officer, director, partner, agent, or em-  
3 ployee thereof, fails to comply with the notification re-  
4 quirement under section 5 of this Act, the United States  
5 district court may order compliance, and may grant such  
6 other equitable relief as the court in its discretion deter-  
7 mines necessary or appropriate, upon application of the  
8 Commission or the Assistant Attorney General.

9 **SEC. 8. RULEMAKING.**

10 The Commission, in consultation with the Secretary,  
11 and with the concurrence of the Assistant Attorney Gen-  
12 eral and by rule in accordance with section 553 of title  
13 5, United States Code, consistent with the purposes of this  
14 Act—

15 (1) may require that the notice described in sec-  
16 tion 5 of this Act be in such form and contain such  
17 documentary material and information relevant to  
18 the agreement as is necessary and appropriate to en-  
19 able the Commission and the Assistant Attorney  
20 General to determine whether such agreement may  
21 violate the antitrust laws;

22 (2) may define the terms used in this Act;

23 (3) may exempt classes of persons or agree-  
24 ments from the requirements of this Act; and

1           (4) may prescribe such other rules as may be  
2           necessary and appropriate to carry out the purposes  
3           of this Act.

4 **SEC. 9. EFFECTIVE DATES.**

5           This Act shall take effect 90 days after the date of  
6           enactment of this Act.

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